Official Journal
of the European Union

EN
L series

2024/778

6.3.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/778

of 5 March 2024

concerning the authorisation of a preparation of protease produced by *Bacillus licheniformis* DSM 33099 as a feed additive for all poultry species for fattening, reared for laying and reared for breeding (holder of authorisation: DSM Nutritional Products Ltd)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of protease (also known as 'subtilisin') produced by *Bacillus licheniformis* DSM 33099. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of protease produced by *Bacillus licheniformis* DSM 33099 as a feed additive for all growing poultry species, requesting that additive to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2023 ([2]) that, under the proposed conditions of use, the preparation of protease produced by *Bacillus licheniformis* DSM 33099 is safe for all poultry species for fattening and reared for laying/breeding, consumers and the environment. The Authority also concluded that the preparation of protease produced by *Bacillus licheniformis* DSM 33099 is not an eye or a dermal irritant but should be considered a respiratory sensitiser, while, in the absence of data, no conclusions could be reached on its skin sensitisation potential. The Authority further concluded that the preparation of protease produced by *Bacillus licheniformis* DSM 33099 has the potential to be efficacious at the level of inclusion of 30 000 NFP protease/kg complete feed for all poultry species for fattening and reared for laying/breeding. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) In view of the above, the Commission considers that the preparation of protease produced by *Bacillus licheniformis* DSM 33099 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for all poultry species for fattening, reared for laying and reared for breeding. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) *EFSA Journal* 2023;21(8):8163.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category: zootechnical additives. Functional group: digestibility enhancers									
4a43	DSM Nutritional Products Ltd	Protease (EC 3.4.21.62)	*Additive composition* Preparation of protease produced by *Bacillus licheniformis* DSM 33099 having a minimum activity of 600 000 NFP ([1])/g. Solid form. *Characterisation of the active substance* Protease (EC 3.4.21.62, also known as 'subtilisin') produced by *Bacillus licheniformis* DSM 33099. *Analytical method* ([2]) For the determination of the protease activity in the feed additive, premixtures and compound feed: colorimetric methods based the enzymatic reaction of protease on the N-Succinyl-Ala-Ala-Pro-Phe p-nitroanilide substrate.	All poultry species for fattening All poultry species reared for laying or reared for breeding	—	30 000 NFP	—	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing and skin protective equipment.	26 March 2034

([1]) One protease unit (NFP) is defined as the amount of enzyme that releases 1 µmol of p-nitroaniline from 1 mM substrate (N-Succinyl-Ala-Ala-Pro-Phe p-nitroanilide) per minute at pH 9,0 and 37 °C.
([2]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en